

REMARKS

The Office Action of June 16, 2009, has been received and reviewed. Claims 21-27 stand rejected. This application is to be amended as previously set forth. All amendments and claim cancellations are made without prejudice or disclaimer. Basis for the amendments, and for new claim 30, can be found throughout the application, for example, at [0078]-[0080] of the as-filed Specification. No new matter has been presented. Reconsideration is respectfully requested.

35 U.S.C. § 112, first paragraph: (written description)

Claims 21-27 stand rejected under 35 U.S.C. § 112, first paragraph, for assertedly containing subject matter which was not described in the specification such that it complies with the written description requirement. Specifically, the Office has asserted that “the issue is whether there is adequate written description support for the complement of the nucleotide sequence which hybridizes to SEQ ID NO:37 and encodes for a portion of a FBPS of *S. suis*,” and concluded that “it appears that Applicants have failed to provide support for an isolated or recombinant nucleic acid molecule comprising a nucleotide sequence of *S. suis* origin wherein the complement of the nucleotide sequence encodes for a portion of a FBPS of *S. suis*.” Office Action of June 16, 2009, at pages 4-7. More specifically, the Office states, “[I]t is the position of the Office that the specification describes the nucleotide sequences of SEQ ID NO:37 and sequences which hybridize to SEQ ID NO:37.” Then, the Office finds that “there is no disclosure of a nucleic acid molecule that hybridizes to SEQ ID NO:37 wherein the complement of the hybridizing nucleotide sequence encodes for a portion of a FBPS of *S. suis*.” *Id.*, at pages 5-6. Applicant respectfully traverses the rejection.

Newly added claim elements may be supported in the specification through express, implicit, or inherent disclosure. MPEP § 2163(I)(B). The analysis of whether the specification complies with the written description requirement calls for the patent examiner to compare the scope of the claim with the scope of the description in order to determine whether applicant has demonstrated possession of the claimed invention. The Office is to compare the scope of amended claims with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention from the standpoint of one of skill in the art at the time the application was filed. *Id.*; See also, e.g., Wang Labs. v. Toshiba Corp., 993 F.2d

858, 865 (Fed. Cir. 1993). Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification. MPEP § 2163(I)(B); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379-80 (Fed. Cir. 1986). If the whole record demonstrates that the written description requirement is satisfied, the Office shall not repeat the rejection in the next Office Action. MPEP § 2163(III)(B).

Possession may be shown by describing an actual reduction to practice of the claimed invention. MPEP 2163(II)(A)(3)(a). And, “an application specification may show actual reduction to practice by describing testing of the claimed invention.” MPEP § 2163(I). Therefore, a specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the elements of the claim and determined that the invention would work for its intended purpose. MPEP § 2163(II)(A)(3)(a); Cooper v. Goldfarb, 154 F.3d 1321, 1327 (Fed. Cir. 1998); UMC Elecs. Co. v. United States, 816 F.2d 647, 652 (Fed. Cir. 1987) (There is a reduction to practice where there is a physical embodiment which includes all elements of the claim). Moreover, as explained by the Federal Circuit, “(1) examples are not necessary to support the adequacy of a written description; (2) the written description standard may be met, even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.” Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006); MPEP § 2163(II)(A)(3)(a).

Written descriptive support for claims 21-27

As amended, claims 21-27 have support in the application to satisfy the requirements of 35 U.S.C. § 112, first paragraph, as, *inter alia*, they are drawn to subject matter the Office has indicated is adequately described.

In the Office Action of June 16, 2009, the Office stated, “[I]t is the position of the Office that the specification describes the nucleotide sequences of SEQ ID NO:37 and sequences which hybridize to SEQ ID NO:37.” *Id.*, at page 5. The Office then seems to assert that the claims are drawn to nucleotide sequences that are complements of SEQ ID NO:37, which sequences encode

an FBPS of *S. suis*. *Id.*, at pages 4-8.¹ As amended, claims 21-27 do not recite the element of “wherein the complement of the nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*.” Therefore, amended claims 21 to 27 are drawn to subject matter the Office has indicated is adequately described, and therefore comply with the 35 U.S.C. § 112, first paragraph. Consequently, applicant respectfully requests the rejection of claims 21-27 under 35 U.S.C. § 112, first paragraph, be withdrawn.

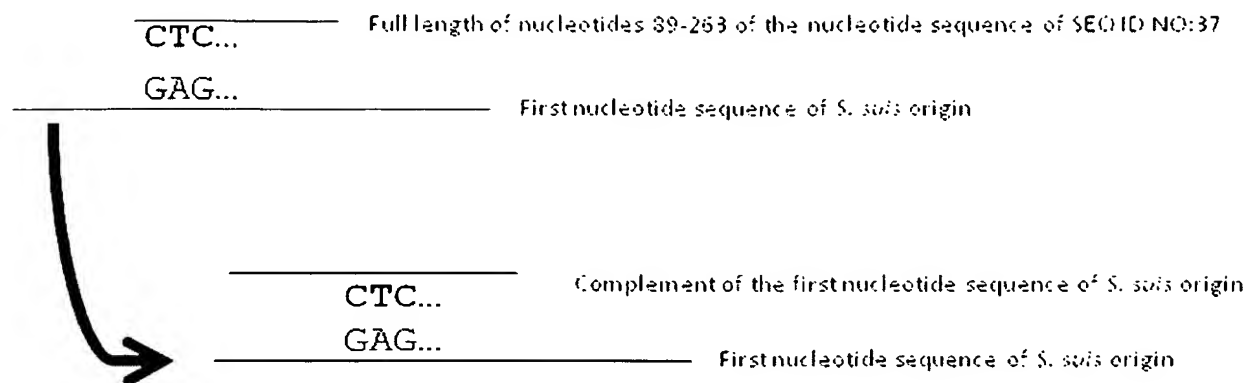
Written descriptive support of new claim 30

New dependent claim 30 has adequate support in the application to satisfy the requirements of 35 U.S.C. § 112, first paragraph, for at least the reason that applicant has provided a first nucleotide sequence of *S. suis* origin which hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37, *wherein the complement of the first nucleotide sequence encodes* for a portion of a FBPS of *S. suis*. As discussed, *supra*, the Office seems to have interpreted the previously submitted claim language as being drawn to a nucleotide sequence that is the complement of SEQ ID NO:37 and encodes a FBPS of *S. suis*. In so doing, the Office has evidently misinterpreted the claims, applicant’s previous arguments, or both. Applicant has amended the claims to clarify the nature of the sequences claimed. As will be set forth in more detail below, the claims are drawn to first sequences which hybridize to SEQ ID NO:37, the complement of the first sequences which encodes a FBPS.

The complement of a nucleotide sequence that hybridizes to nucleotides 89-263 of SEQ ID NO:37 must necessarily comprise sequences of high homology to nucleotides 89-263 of SEQ ID NO:37. Nucleotides 89-263 of SEQ ID NO:37 are a portion of an *S. suis* FBPS. Therefore, the complement of a sequence which hybridizes to nucleotides 89-263 of SEQ ID NO:37 must encode a portion of an *S. suis* FBPS. This is illustrated in the following diagram.

¹ *See, e.g.*, at page 4 (“Applicants submit that complement of the described nucleic acid sequence that hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37 under the recited conditions *would have a complement* that necessarily includes a nucleotide sequence that encodes for a portion of a FBPS of *S. suis*.”) (emphasis added); at page 5 (“Applicant’s argument that nucleotides 89-263 of SEQ ID NO:37 encode for a portion of FBPS of *S. suis* thus *the sequence’s complement would necessarily include a nucleotide sequence that encodes* for a portion of a FBPS of *S. suis* is not persuasive.”) (emphasis added).

Diagram of sequences in claim 30



As is clear from the foregoing diagram, the first nucleotide sequence of *S. suis* origin that hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37 comprises sequences *complementary to* the full length of nucleotides 89-263 of SEQ ID NO:37. This is the case, because DNA is present as a double-stranded molecule in the cell, wherein there is both a sense and anti-sense strand with bases forming bonds with complementary bases on the opposite strand in A-T and G-C base pairs. Nucleotides 89-263 of SEQ ID NO:37 are a portion of the *S. suis* fbps gene. Therefore, both this sequence and its anti-sense complement are present in the double-stranded *S. suis* genome. As is also clear from the foregoing diagram, the complement of the first nucleotide sequence of *S. suis* origin (which hybridizes to nucleotides 89-263 of SEQ ID NO:37) must comprise sequences highly homologous to the full length of nucleotides 89-263 of SEQ ID NO:37. Therefore, applicants most respectfully submit that the statements presented by the Office in the Office Action of June 16, 2009, are not on point. For example, at page 5 of the Office Action, second paragraph, the Office argues that applicant suggests the complement of SEQ ID NO:37 must encode a portion of FBPS. Respectfully, this is incorrect. As the foregoing diagram illustrates, a sequence that hybridizes to SEQ ID NO:37 will be at least highly homologous to SEQ ID NO:37's complement. The complement of that hybridizing nucleic acid, then, will be highly homologous to SEQ ID NO:37 itself.

Additionally, the Office has asserted that "there is no description of the complement of the nucleotide sequence which hybridizes to SEQ ID NO:37 under the instantly claimed

conditions (and) encodes for a portion of a FBPS of *S. suis*.” *Id.*, at page 5. Respectfully, this is also incorrect. It is plainly indicated in the Specification, *inter alia*, in the section entitled, “Cloning of the *S. suis* fbps gene,” that the *S. suis* fbps gene (GenBank accession no. AF438159) was identified by probing the *S. suis* genome with SEQ ID NO:37, and that gene encodes a functional fibronectin-/fibrinogen-binding protein of *Streptococcus suis*. *Id.*, at [0078] - [0082]. Nucleotides 89-263 of SEQ ID NO:37 are a portion of the identified fbps gene. The Office should not be confused by the fact that the fbps gene was identified by hybridization with a partial sequence from the fbps gene. This does not indicate that the fbps gene is in an anti-sense orientation with respect to nucleotides 89-263 of SEQ ID NO:37. Because DNA is a double-stranded molecule where each strand is the complement of the other, a probe which identifies the complement of a gene necessarily identifies the gene itself. This is common knowledge among those of ordinary skill in the art.

The working examples provided in the Specification, for example, at [0078] - [0082], unequivocally demonstrate to one of skill in the art that applicant was in possession of the claimed nucleic acid molecules through an actual reduction to practice.

For at least the foregoing reasons, applicant respectfully submits that new claim 30 complies with the requirements of 35 U.S.C. § 112, first paragraph, and requests allowance of this claim. Because the prior rejection of claim 21, which was drawn to similar subject matter, seems to have been based in large part on a misunderstanding regarding the scope of the claim, the Office is respectfully requested to contact applicant’s representative at the phone number given herein prior to issuing a new Office Action if applicant’s present remarks have not eliminated the confusion.

35 U.S.C. § 112, first paragraph: (new matter)

Claims 21-27 stand rejected as new matter under 35 U.S.C. § 112, first paragraph, for assertedly containing subject matter which was not described in the specification such that it complies with the written description requirement. Applicant respectfully traverses the rejection.

The rejection of claims 21-27 as new matter should be withdrawn for the same reasons the aforementioned written description rejection should be withdrawn. In view of the above remarks, applicant submits that [0066]; and [0078] - [0082] of the as-filed Specification provide

more than ample support for the recited hybridization conditions and nucleotide sequences.

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicant's attorney at the address or telephone number given herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Allen C. Turner", with a long horizontal flourish extending to the right.

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